

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Thomas NILSSON, et al.

SERIAL NO: New Application

GAU:

FILED: Herewith

EXAMINER:

FOR: A MEDICAL PRODUCT

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

REFERENCES

- ☒ The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

RELATED CASES

- ☐ Attached is a list of applicant's pending application(s) or issued patent(s) which may be related to the present application. A copy of the patent(s), together with a copy of the claims and drawings of the pending application(s) is attached along with PTO 1449.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

CERTIFICATION

- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

DEPOSIT ACCOUNT

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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MAIER & NEUSTADT, P.C.


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DOCKET NO.: 246424US8

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Thomas NILSSON, et al.

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FILED: HEREWITH

FOR: A MEDICAL PRODUCT

STATEMENT OF RELEVANCY

Reference AW listed on the attached Form PTO 1449 is discussed at page 4, lines 22-25 of the specification.

Reference AX listed on the attached Form PTO 1449 is discussed at page 5, lines 8-11 of the specification.

Reference AY listed on the attached Form PTO 1449 is discussed at page 5, lines 11-13 of the specification.

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| Form PTO 1449 (Modified) | | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | ATTY DOCKET NO. 246424US8 | | SERIAL NO. New Application | |
| LIST OF REFERENCES CITED BY APPLICANT | | | | APPLICANT Thomas NILSSON, et al. | | | |
| | | | | FILING DATE Herewith | | GROUP | |
| U.S. PATENT DOCUMENTS | | | | | | | |
| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB CLASS | FILING DATE IF APPROPRIATE |
| | AA | | | | | | |
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| FOREIGN PATENT DOCUMENTS | | | | | | | |
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| | AV | | | | | | |
| OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.) | | | | | | | |
| | AW | COLLEGE TER BEOORDELING VAN GENEESMIDDELEN MEDICINES EVALUATION BOARD; PUBLIC ASSESSMENT REPORT; "Spiriva 18 µg, inhalation powder in hard capsules"; May 21, 2002; pp. 1-28 | | | | | |
| | AX | Guidance for Industry; "Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products"; Chemistry, Manufacturing, and Controls Documentation; 1998 | | | | | |
| | AY | Guidance for Industry; "Stability Testing of Drug Substances and Drug Products"; Draft Guidance B; 1998 | | | | | |
| | AZ | | | | | <input type="checkbox"/> Additional References sheet(s) attached | |
| Examiner | | | | | Date Considered | | |
| *Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | | | | | | | |